REMARKS

Claims 1-40 are in the case and presented for reconsideration. Claim 1 has been amended. The support for this amendment is found in the Applicant's Specification, for example, page 16, lines 17-18. No new matter has been added.

The Information Disclosure Statement filed August 24, 1999 has not been considered in view of 37 C.F.R. § 1.98(a)(2). Accordingly, a new Information Disclosure Statement and P.T.O. Form 1449 are being provided in order to satisfy the requirements of 37 C.F.R. § 1.98(a)(2) and (d). The Applicant would like to point out the present application is a Continuation-in-Part Application under 35 U.S.C. § 120 of prior Patent Application No. 09/019,453 filed February 5, 1998, now issued U.S. Patent No. 6,309,370.

Claims 1, 2, 12, 13, 14, 15, 32, 35 and 38 have been rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent 6,283,951 (Flaherty et al.). With respect to this rejection, the Examiner has stated:

> Flaherty discloses systems and methods that use the cardiovascular system as a conduit to deliver drugs, such as therapeutic drugs, genes, growth factors and the like, directly to selected tissue regions within the body. (Col. 1, line 10-15) "Drug" as defined herein includes any therapeutic drugs, genetic materials, growth factors, cells, e.g. myocites, vectors carrying growth factors, and similar therapeutic agents or substances that may be delivered within a patient's body for any therapeutic, diagnostic or other procedure. In one aspect of the present invention, a transvascular catheter system is provided that generally includes a catheter, a drug delivery element, an orientation element, and possibly a puncturing element and/or an imaging element. (Col. 3 line 54-62)
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> The imaging element is an ultrasound transducer within the catheter which preferably including the orientation element which selects tissue region and/or other landmarks within the vessel or the surrounding tissue. Where the puncturing element is a drug delivery needle, the needle may be deployed, penetrating a wall of the blood vessel and entering the tissue region, and the drug may be delivered through a lumen in the needle. (Col. 5, lines 18-25)

With respect to the above-outlined rejection, the Applicant respectfully traverses as follows. Flaherty et al. describes systems and methods for delivering drugs to selected locations

within the body. As noted by the Examiner, the term "drug" includes any therapeutic drugs, genetic materials, growth factors, cells, e.g. myocites, vectors carrying growth factors, and similar therapeutic agents and substances. Col. 3, lines 53-56. However, contrary to the Examiner's interpretation of this reference, the "orientation element" described in Flaherty et al. is not a position sensor capable of generating signals responsive to the position of the catheter. But rather, the "orientation element" is either a "cage structure that includes a plurality of struts extending axially along the distal portion" of the catheter (in one embodiment), or "a marker that may be imaged using an external imaging system, and preferably a pair of markers disposed opposite one another on the periphery, either instead of or preferably in addition to the cage structure." Col. 4, lines 50-64. Thus, the "orientation element" of Flaherty et al. is entirely incapable of being used as a position sensor which generates signals responsive to the position of the catheter. Moreover, Flaherty et al. clearly does not describe, suggest or infer utilizing a position sensor which generates signals responsive to the position of the catheter wherein the signals were used to generate position and orientation coordinates such as found in the Applicant's claimed invention (as amended).

Claims 3-11 have been rejected under 35 U.S.C. § 103(a) as being unpatentably over Flaherty in view of U.S. Patent 5,865,738 (Morocos et al.). Claims 18, 19, 21-24 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Flaherty as applied to claim 1 above, and further in view of U.S. Patent 6,258,789 (German et al.). Claims 16-17 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Flaherty as applied to claim 1 above, and further in view of U.S. Patent 5,833,978 (Tremblay et al.). Claims 16 and 20 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Flaherty as applied to claim 1 above, and further in view of U.S. Patent 5,328,470 (Nabel et al.). Claims 6, 7, 8, 12, 15, 16, 17 and 25-31 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Flaherty as applied to claim 1 above, and further in view of U.S. Patent 6,277,082 (Gambale et al.). Claims 33, 36 and 39 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Flaherty as applied to claim 1 above, and further in view of U.S. Patent 5,960,796 (Kremer). Claims 34, 37 and 40 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Flaherty as applied to claim 1 above, and further in view of U.S. Patent 4,578,061 (Lemelson).

With respect to these rejections, there is nothing in either Flaherty or any of the other cited prior art references that will lead one of ordinary skill to combine these references in the manner suggested by the Examiner. Additionally, even if they were combined and applied against the Applicant's claimed invention, none of these references either alone or in combination with each other, teach, suggest or infer the Applicant's claimed invention of claim 1 (amended) and the dependent claims therefrom (either directly or indirectly). Particularly, none of these cited prior art references, either alone or in combination, describe, suggest or infer a method for delivering a cell to a heart of a patient comprising the steps of providing an apparatus for intracardiac drug administration comprising a catheter wherein the catheter has at least one position sensor which generates signals responsive to the position of the catheter and the signals are used to generate position and orientation coordinates, and a drug delivery device for delivering the cell; inserting the catheter into a chamber of the heart at a site; and delivering the cell to the site with the drug delivery device based on position and orientation coordinates in response to the signals from the position sensor. These novel combination of steps of the Applicant's claimed method are simply not addressed nor inferred from any of these cited prior art references.

Accordingly, by the Amendment and for the reasons listed above, the Applicant's claimed invention is believed to be patentably distinct and non-obvious over the cited prior art references and favorable action is respectfully requested.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page(s) is/are captioned "Version with markings to show changes made".

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claim 1 (Amended) A method for delivering a cell to a heart of a patient comprising the steps of:

providing an apparatus for intracardiac drug administration comprising a catheter, said catheter having at least one position sensor which generates signals responsive to the position of said catheter, said signals being used to generate position and orientation coordinates, and a drug delivery device for delivering said cell;

inserting said catheter into a chamber of said heart at a site;

delivering said cell to said site with said drug delivery device based on position and orientation coordinates in response to said signals from said position sensor.